in condition for allowance. While applicants certainly understand that an Examiner is entitled to, and certainly should, search for additional prior art of particular relevance, in this case the Examiner has merely ignored the prior history of this application, and issued a final rejection based upon prior art which was already in the record and considered by the parties. Indeed, the previously cited art can have no impact on the allowable nature of these claims. The Examiner's actions are thus inexplicable in this case, and at the very least it is respectfully requested that the Examiner carefully reconsider his position irrespective of the final nature of this rejection. In that regard, the Examiner's contention that the applicants' amendment somehow necessitated this rejection is without any support. In addition to the fact that the amendment set forth in the July 9, 2001, response was discussed in detail and agreed to by the Examiner, the prior art cited was already of record, and at the very least could have been discussed at the personal interview. In any event, since this alleged prior art can have no real impact on the patentable nature of these claims, it is respectfully requested that the Examiner reconsider his unsupportable position, and finally allow the case as was agreed to at the aforementioned personal interview.

Turning to the rejection, claims 84 and 85 have now been rejected as being anticipated by Miranda *et al.* The Examiner contends that Miranda *et al.* teaches a transdermal comprising an active and a mixture of polymers; namely, an acrylate polymer and a polysiloxane, citing the Abstract. Tetracaine and chlorpheniramine are said to be specified, citing column 11, lines 5 and 25 thereof. This rejection is respectfully traversed in view of the above arguments, and for the additional reasons set forth hereinafter.

The overall nature of the Miranda *et al.* reference relates to transdermal drug delivery compositions which comprise

blends of polymers having different solubility parameters, and which are preferably immiscible with each other, which may thus be used to adjust the solubility of the drug in the adhesive system. It is thus clear from the outset that the objectives of this reference are quite different from those of the present invention. As has thus been pointed out throughout this application, the present invention, as exemplified by the pending claims, relates to the use of highly plasticizing drugs and the express need to use adhesive formulations consisting essentially of hydrophobic polymers, to the express exclusion of certain specified solvents, in such an environment.

It is further noted that in the background section of the Miranda *et al.* patent, it is stated that drug concentration in monolithic transdermal systems can vary widely. It is thus noted that with certain drugs which are effective in low doses, the "low concentrations of medicament typically do not critically effect the adhesion, tack, and shear resistant properties of the adhesive." (Column 2, lines 64-66.) The background secton of Miranda *et al.* then goes on to note that there is a need for adhesive compositions for transdermal delivery which can selectively incorporate low concentrations of drugs and deliver them at adequate and controlled rates. It is precisely these types of drugs, in accordance with the present invention, which are highly plasticizing in their character, and which can be incorporated in large amounts in accordance with the present invention, but which are not the subject of Miranda *et al.* Indeed, Miranda *et al.* make no suggestion that their invention could provide such a result.

Turning to the specifics of the Miranda *et al.* disclosure, the objectives of the present invention are achieved by specifically requiring the exclusive use of hydrophobic polymers in connection with these particular types of plasticizing drugs; namely, those defined in these claims which

are of low molecular weight in liquid at or about room temperature. There is certainly no disclosure in Miranda *et al.* of such compositions. Quite to the contrary, many of the adhesives shown in Miranda *et al.* are quite hydrophilic and would not work in accordance with the present invention. There is thus clearly no teaching of the significance of using hydrophobic polymers in accordance with the specific claimed compositions of the present invention. Even more particularly, in each of the compositions in every example in the Miranda *et al.* reference, a volatile solvent is employed, including propylene glycol, other low molecular weight glycols, and the like. These compounds are, of course, specifically excluded from the present claims. The complete failure of Miranda *et al.* to suggest the presently claimed invention in this regard is not surprising, however, in view of the very different objectives of the patent as is set forth above.

The present specification discloses the nature of the hydrophobic polymers required by the pending claims, and the basis for the present invention in terms of applicants' discovery of the poor adherence properties of a number of adhesives disclosed therein. On the other hand, the various polymers disclosed in Miranda *et al.* include a number of polymers, such as DURATAK 80-1194, and the like, which have been shown to be entirely unworkable in accordance with the present invention, as shown in the specification.

Once again, Miranda *et al.* in no way teaches or suggests the specific claimed invention set forth in claims 84 and 85. It does not teach the basic requirement of a delivery system consisting essentially of the blend set forth in claim 84 for the purpose of producing a product which includes the type of highly plasticizing drug components to which these claims are directed in significant commercial amounts while obtaining a product which has highly desirable adhesive properties. To the

contrary, there is no teaching of a transdermal system which includes hydrophobic polymers, and which is substantially free of water and liquids having the required normal boiling point set forth in claim 84; *i.e.*, the volatile solvents such as those specifically required by every example in Miranda *et al.*

It is therefore respectfully submitted that pending claims 84 and 85, as was previously agreed to by the Examiner, are clearly directed to patentable subject matter over all of the cited references, including Miranda *et al.* Therefore, reconsideration and allowance of this application is respectfully solicited. Once again, however, if the Examiner still does not believe that this application can be allowed, for any reason, it is respectfully requested that he telephone applicants' attorney at (908) 654-5000 in order to overcome any further objections which the Examiner may have at this time.

Finally, if there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Respectfully submitted,

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